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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,279	06/25/2003	Lee Michael Teras	9286	4437

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EXAMINER

HENDRICKS, KEITH D

ART UNIT	PAPER NUMBER
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1761

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/603,279

Applicant(s)

TERAS ET AL.

Examiner

Keith Hendricks

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8-15, 21-25 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-15, 21-25 and 41-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 07, 2006 has been entered.

Claim Rejections - 35 USC § 112

i) The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

a) Claims 1-5, 8-10, 11-15, 21-25 and 41-44 (all pending) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding the production of a corn-based food product (a) to which an asparagine-reducing enzyme has been added, or (b) to which an asparagine-reducing enzyme has not been added (i.e. the "control"), pages 29 and 30 of the specification state that "the control sample is prepared in exactly the same manner as the enzyme-treated sample, with the exception that enzyme is not added."

Applicant's current amendment to the claims adds the phrase "... a substantially similar corn-based food material processed in a similar manner without an asparagine-reducing enzyme."

There is no support or rationale for applicant's attempt to improperly broaden the disclosure of the invention by said claim amendment. The specification clearly does not provide support for this liberty taken by applicant to unduly broaden the original disclosure by inserting such into the claims. The

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specific phrasing found at pages 29 and 30 appears to be the only passage within the disclosure related to such a concept.

Further, it is strongly recommended that in their response, applicant provide a remark noting from where any amended claim language finds support in the specification. Such measures would assist the examiner in making accurate determinations of claim support, would greatly reduce the amount of time necessary for the examiner to scrutinize the specification, and could potentially avoid unnecessary new matter-type rejections. Further in turn this would serve applicant well during prosecution of the application.

b) Claim 10 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim (a) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, and (b) further, the claim contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Method claim 10 recites the phrase “reducing the level of acrylamide in corn-based food products.” Initially, this actual method step would be impossible for one skilled in the art to carry out, for in order to perform the claimed method, the corn-based food product must have an initial amount of acrylamide. However, the (natural) starting corn-based food composition does not possess acrylamide prior to heating. Therefore, addition of an asparagine-reducing enzyme could not result in any reduction of acrylamide in the corn-based food product, as presently recited. Thus the claim fails to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

NOTE: Claim 10 may be contrasted with method claims 1 and 5, which are directed to methods for “reducing the level of asparagine in a corn-based food product.” As these corn-based food products inherently possess *asparagine* prior to said processing, they are not included in this particular rejection.

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ii) The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8-10, 11-15, 21-25 and 41-44 (all pending) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- **Claims 1, 5, 10, 41 and 43**

Claims 1, 5, 10, 41 and 43 are indefinite for the recitation of the added phrase "... a substantially similar corn-based food material processed in a similar manner without an asparagine-reducing enzyme."

The terms "similar" and "substantially similar" are relative terms which render the claims indefinite. The terms are not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. The specification does not provide a teaching of which steps would be included or excluded by a "similar manner" of processing; nor does the specification provide guidance regarding how one skilled in the art would determine if a corn-based food material would be "similar" enough to meet the claim limitations, let alone one which was "substantially similar" in some way. Regarding the phrase "processed in a similar manner", it is unclear as to (a) what steps would be required to make a similar product, especially considering those claims which are directed to an article of commerce comprising a container and corn chips, (b) to what degree of "similarity" these steps must be, and (c) what properties of a process step are considered in order to make it "similar" to another.

If applicant intends the claims to convey that the second comparison corn-based food material "is prepared in exactly the same manner as the enzyme-treated sample, with the exception that enzyme is not added" (pg. 29 and 30, specification), then this is not clear from the current claim language.

* NOTE: Regarding method claims 1 and 5, it is believed that the added 'comparison-type' language would not be necessary, as these claims are directed to "a method for reducing the level of asparagine in a corn-based food material... comprising adding the asparagine-reducing enzyme to the food material before heating." As the original corn-based food material inherently contained asparagine, no comparison to a control food material without the added enzyme would be necessary, and in fact, is not recommended.

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- **Claim 10**

Method claim 10 is indefinite for the recitation of the phrase “reducing the level of acrylamide in corn-based food products.” Initially, this actual method step would be impossible for one skilled in the art to carry out, for in order to perform the claimed method, the corn-based food product must have an initial amount of acrylamide. However, the (natural) starting corn-based food composition does not possess acrylamide prior to heating. Therefore, addition of an asparagine-reducing enzyme could not result in any reduction of acrylamide in the corn-based food product, as presently recited.

- **Claims 11-15 and 21-25**

Claims 11-15 and 21-25 are indefinite for the recitation of the phrase “the corn-based food material according to claim 1” (or claim 10, etc.). Claims 1 and 10 are directed to methods, not products/materials. Thus the metes and bounds of claims 11-15 and 21-25 are unclear and indefinite. It is recommended that the claims be amended according to the following configuration: “a corn-based food material produced by the method according to claim 1, wherein...”, etc.

- **Claims 21-25 and 41-44**

The term “reduced”, in product claims 21-25 and 41-44, is a relative term which renders the claims indefinite. The term “reduced” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Applicant's arguments filed April 07, 2006, have been fully considered but they are not persuasive. Applicant states that the claims have been amended to clarify the meaning of the term “reduced.” However, in light of the rejections set forth previously on the record regarding this term, as well as those explained above, this is not deemed persuasive and the rejection is maintained.

* Note that claims 11-15 are not included in this particular rejection, as they are directed to a food product which (if amended to clarify the language as recommended above) depend from a method which reduces the amount of asparagine present in the corn-based food product.

Claims 41-44

The term “the consumer” lacks a clear antecedent basis within the claims. It is suggested that this phrase be amended to recite “a consumer.”

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 8-15, 21-25 and 41-44 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Elder et al. (Pub. No. US 2004/0058054). The reference and rejection are incorporated as cited in a previous Office action.

Applicant's arguments filed April 07, 2006, have been fully considered but they are not persuasive.

In response to applicant's statement at page 6 of the reply, regarding establishing a prima facie case of obviousness, it is noted that no substantial modification of the reference is necessary. No secondary reference teaching is required to modify the primary reference and meet the claim limitations. The rejection was made under 35 U.S.C. 103(a) because, while the reference did not specifically describe actually carrying out the method steps necessary to produce the food product as instantly claimed, it does provide the necessary teachings in order to carry out such methods described therein. In other words, the reference teaches how to carry out the invention; it simply did not provide examples for each and every possible method and resultant food product or article, and as such, the rejection was made under 35 U.S.C. 103(a) such that it would have been obvious to follow these teachings and suggestions to carry out the invention disclosed therein.

Regarding applicant's assertion at page 6 of the response that the reference never achieved a reduction of asparagine or acrylamide in food, this has been previously addressed of record. See pages 4-7 of the final Office action of February 24, 2005.

Regarding applicant's assertion at page 7 of the response that Elder et al. never explained the "nature of this contact" of the enzyme with the food material, this has been previously addressed of record. See pages 4-7 of the final Office action of February 24, 2005. Further, applicant's comments at page 7 of the response, with reference to page 5 of the specification, are not deemed persuasive. Applicant alleges that their disclosure is "much more robust and definitive" than that of Elder et al., because the specification generally describes such actions where "the enzyme may be added to the corn-

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based food material in any suitable manner, such as directly (for example, sprinkled, poured or sprayed on the corn-based food material, or the corn-based food material can be soaked in an enzyme solution) or indirectly.” This is not deemed persuasive for the reasons of record. It is not agreed that the addition of the enzyme by sprinkling, pouring or spraying on the food material, or soaking the food material in an enzyme solution, would constitute a ““much more robust and definitive” disclosure. Further, this would not serve to provide a patentable concept over the teachings of Elder et al. One of ordinary skill in the art would readily know how to add the enzyme to the food material, as the very nature of the use of isolated enzyme compositions over the past several decades necessarily involves these or other rudimentary application techniques. Furthermore, in a related manner, the application of nearly any food-related composition to a base material, such as a sauce to a meat product to be cooked, would have been well-understood and known by anyone who has had experience with such food products, and thus applicant’s assertion that somehow one of ordinary skill in the art would not know how to apply an enzyme to a food material, is not deemed persuasive.

Regarding applicant’s statement at page 7 of the response concerning the alleged “difficulty”, and “much work and energy” needed to penetrate the cell walls of a corn-based food material, this is not deemed persuasive for the reasons of record, specifically those found at page 5 of the final Office action of February 24, 2005. Further, it appears that applicant is alleging that one of ordinary skill in the art would not be aware of the fact that, in order to effectively apply the enzyme to the food material, a mixing step could be utilized, for example. This is simply not deemed persuasive. Regardless, such limitations argued by applicant are not found within the claims.

At pages 7-8 of the response, applicants state that the examiner “is using the wrong test for obviousness”, and has not given proper weight to the claim limitations regarding the written message and container as recited in the claims.

This is not deemed persuasive for the reasons of record. Initially, regarding the container as part of the claimed invention, this has been addressed of record. See page 7 of the February 24, 2005 Office action.

Regarding the particular message “associated with the container” (unclear whether typed, written, scribbled or encoded, and whether this is actually present on the container, or perhaps somewhere on a display shelf near the container, i.e. “associated with” such), this, too, has been addressed of record. Again, it would have been obvious to one of ordinary skill in the art to have packaged and appropriately

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labeled the food products produced by Elder et al. Packaging and labeling techniques were well-known and common in the art, especially regarding any potential special feature that might draw the interest of the consumer. Regarding the particular message, it is noted that the printed word itself would not significantly change the claimed article of matter, and would not provide a patentable distinction, *per se*, over the known prior art package materials and methods.

This statement does not imply in any way that the examiner failed to consider this part of the claimed invention. In fact, by addressing the point in the first Office action and throughout prosecution, this demonstrates that such was indeed considered.

The printed matter on the label of the instantly-claimed container is not integral to the function of the claimed article, for example, as opposed to a situation where the printed matter serves as an indicator for measurement, thus affecting the use and function of the article as a whole. Such is simply not the issue in the instant case. A simple message on the claimed article of commerce would not alter or change the tangible, material functions of the article, namely those involving the corn-based food product and the container. A message which "informs the consumer that the corn-based food product has a reduced level of acrylamide" (or asparagine) would not functionally or significantly alter the article, and would not patentably differ from the same article with a message of "tasty corn food" written on a label, for example. While the words on the container may describe that which is in the container, they do not provide any actual function related to the container or snack chip therein. The mere arrangement of the words on a container, as applicant has claimed, do not amount to a functional property of the invention.

Finally, applicant is referred to MPEP 2112.01, part III, which states

where the only difference between a prior art product and a claimed product is printed matter that is not functionally related to the product, the content of the printed matter will not distinguish the claimed product from the prior art. *In re Ngai*, **>367 F.3d 1336, 1339, 70 USPQ2d 1862, 1864 (Fed. Cir. 2004). See also *In re Gulack*, 703 F.2d 1381, 1385-86, 217 USPQ 401, 404 (Fed. Cir. 1983)("Where the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability [T]he critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate.").

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Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

i) Claims 41-44 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-12 of copending Application No. 10/606,260.

ii) Claims 1-5 and 7-44 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 and 42-50 of copending Application No. 10/606,137.

iii) Claims 11-44 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-14 of copending Application No. 10/603,978.

Applicant's comments filed April 07, 2006 have been fully considered but they are not persuasive.

Applicant's comments reflect those presented previously, and the rejections are maintained for the reasons of record.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (571) 272-1401. The examiner can normally be reached on M-F (8:30am-6pm); First Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Milton Cano can be reached on (571) 272-1398. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KEITH HENDRICKS
PRIMARY EXAMINER